

## REMARKS

Before entry of this Amendment, claims 1 – 9 and 12 – 25 were pending in the application. After entry of this Amendment claims 1 – 9 and 12 – 25 remain pending under examination. The number of total claims has not been increased, and the number of independent claims has not been increased beyond the number for which payment previously had been made.

Applicant has carefully considered the Examiner's Final Action of February 3, 2010, and the references cited therein. The following is a brief summary of the Action. Claims 1-6, 21 and 22 were rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,545,179 (hereafter Williamson). Claims 7 and 13 were rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson. Claims 8, 9, 12, 16 and 23 were rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson in view of Kieturakis (USP 5,667,479). Claims 14, 17 and 18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson and Kieturakis, and further in view of Haber et al (USP 4,850,953). Claim 15 was rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson in view of Mulhauser et al (US Pub. 2003/0181879). Claims 19 and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson and Kieturakis and further in view of Salama (USP 6,527,755). Claims 24 and 25 were rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson and Kieturakis and further in view of Kim (USP 5,569,216).

For the reasons explained below, applicant respectfully traverses the rejection of claims 1-6, 21 and 22 under 35 U.S.C. 102(b) as being anticipated by Williamson.

Lines 1-2 of paragraph 4 on page 2 of the February 2010 Final Office Action contends that Williamson teaches a closing system for a natural or artificial anus. However, this statement is inaccurate, and Williamson in fact never mentions the word anus or the word anal.

The present invention pertains to a closing system for a natural or artificial anus. However, Williamson discloses an endoscopic access assembly 20 through which a surgical instrument 24 (FIG. 11) can be delivered through the body wall 21.

Applicant's only independent claim, claim 1, requires:

a first cylindrical sleeve defining a first lumen with a first diameter and a second cylindrical sleeve defining a second lumen with a second diameter, said second sleeve having a portion nesting within the first lumen of said first sleeve, an inflatable balloon having a generally toroidal structure formed of a hose segment \* \* \* and defining a first end and a second end, which hose segment is inverted into itself, whereby its two ends extend generally coaxially with each other and said first end is connected to said first sleeve and forms a continuous pathway with said first lumen and said second end is connected to said second sleeve and forms a continuous pathway with said second lumen.

Lines 2-24 of paragraph 4 on pages 2-3 of the February 2010 Final Office Action contend that Williamson discloses (emphasis added):

a first cylindrical **outer sleeve** (figure 6, **item 35**) defining a first lumen with a first diameter (figure 6, item 41) and a second cylindrical **inner sleeve** (figure 6, **item 34**) defining a second lumen with a second diameter (figure 6, item 38), said second sleeve having a portion nesting within the first lumen of said first sleeve (figure 6), an inflatable thin-walled polyurethane (column 5, lines 42-44) **balloon** (figure 5, **item 26**), preformed with two connection ports or ends (figure 6, **items 34 and 35**), having a generally toroidal structure, formed of a hose segment with a two-dimensional surface and defining a first and a second end, which hose segment is inverted into itself to define an inner wall and an outer wall and wherein the portion of the inner wall of the inflated

balloon disposed internally of the wearer defining an internal area configured without any rigid guide shaft therein that otherwise might project into the wearer's intestine (figure 6), whereby its two ends extend generally coaxially with each other and said first end is connected to said first sleeve (figure 6) and forms a continuous pathway with said first lumen and said second end is connected to said second sleeve and forms a continuous pathway with said second lumen;

However, the above attempt of the Final Office Action to read claim 1 limitations on the structure illustrated in Williamson FIGs. 5 and 6 has a fatal flaw. Some of the structures in Williamson must be double counted in order to satisfy all of the limitations in claim 1.

In particular, the Final Office Action first identifies the outer sleeve as item 35 and the inner sleeve as item 34 and then identifies the balloon as item 26. However, item 26 is comprised of items 34 and 35, and therefore the Final Office Action has double counted items 34 and 35 in order to anticipate all of the limitations of claim 1. In other words, the Final Office Action uses the same structures to satisfy both the outer and inner sleeves and the balloon required by claim 1. Thus, either Williamson lacks an outer sleeve and an inner sleeve or Williamson lacks a balloon. But Williamson cannot use the same structure to anticipate more than one of these limitations of claim 1. In fact, Williamson does not disclose an inner sleeve nested within an outer sleeve and connected to a balloon with a toroidal structure.

Applicant therefore respectfully submits that claims 1-6, 21 and 22 are patentable under 35 U.S.C. 102(b) over Williamson.

For the reasons explained below, applicant respectfully traverses the rejection of claims 7 and 13 under 35 U.S.C. 103(a) as being unpatentable over Williamson.

The deficiency in Williamson noted above precludes Williamson from rendering claims 7 and 13 obvious to the person of ordinary skill.

Applicant therefore respectfully submits that claims 7 and 13 are patentable under 35 U.S.C. 103(a) over Williamson.

For the reasons explained below, applicant respectfully traverses the rejection of claims 8, 9, 12, 16 and 23 under 35 U.S.C. 103(a) as being unpatentable over Williamson in view of Kieturakis.

Kieturakis fails to compensate for the deficiency in Williamson noted above.

Applicant therefore respectfully submits that claims 8, 9, 12, 16 and 23 are patentable under 35 U.S.C. 103(a) over Williamson in view of Kieturakis.

For the reasons explained below, applicant respectfully traverses the rejection of claims 14, 17 and 18 under 35 U.S.C. 103(a) as being unpatentable over Williamson and Kieturakis, and further in view of Haber et al.

Haber et al fails to compensate for the deficiency in Williamson and Kieturakis noted above.

Applicant therefore respectfully submits that claims 14, 17 and 18 are patentable under 35 U.S.C. 103(a) over Williamson and Kieturakis, and further in view of Haber et al.

For the reasons explained below, applicant respectfully traverses the rejection of claim 15 under 35 U.S.C. 103(a) as being unpatentable over Williamson in view of Mulhauser et al.

Mulhauser et al fails to compensate for the deficiency in Williamson noted above.

Applicant therefore respectfully submits that claim 15 is patentable under 35 U.S.C. 103(a) over Williamson in view of Mulhauser et al.

For the reasons explained below, applicant respectfully traverses the rejection of claims 19 and 20 under 35 U.S.C. 103(a) as being unpatentable over Williamson and Kieturakis and further in view of Salama.

Salama fails to compensate for the deficiency in Williamson and Kieturakis noted above.

Applicant therefore respectfully submits that claims 19 and 20 are patentable under 35 U.S.C. 103(a) over Williamson and Kieturakis and further in view of Salama.

For the reasons explained below, applicant respectfully traverses the rejection of claims 24 and 25 under 35 U.S.C. 103(a) as being unpatentable over Williamson and Kieturakis and further in view of Kim.

Kim fails to compensate for the deficiency in Williamson and Kieturakis noted above.

Applicant therefore respectfully submits that claims 24 and 25 are patentable under 35 U.S.C. 103(a) over Williamson and Kieturakis and further in view of Kim.

Applicant respectfully requests reconsideration and reexamination of claims 1 – 9 and 12 – 25, as presented herein, and submits that these claims are in condition for allowance and should be passed to issue.

If any fee or extension of time is required to obtain entry of this Amendment, the undersigned hereby petitions the Commissioner to grant any necessary time extension and authorizes charging Deposit Account No. 04-1403 for any such fee not submitted herewith.

Respectfully submitted,

DORITY & MANNING, P.A.

DATE: March 29, 2010

BY: James M. Bagarazzi  
JAMES M. BAGARAZZI  
Reg. No. 29,609  
P.O. Box 1449  
Greenville, SC 29602-1449  
(864) 271-1592